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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,489	05/25/2000	Ray W. Wood	029318/0596	7761

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07/30/2002

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/577,489

Applicant(s)

WOOD ET AL.

Examiner

Sabiha Naim Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 10-46 is/are pending in the application.
- 4a) Of the above claim(s) 10-27 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 28-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 10-27 and 46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 and 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 10-46 are pending.

Claims 28-45 are examined; others are withdrawn from consideration as non-elected invention. New claim 46 is drawn to diagnostic agent, which is a non-elected invention.

Response filed in paper no. 11 and election of group I and species "corticosteroid" with traverse is hereby acknowledged. In order to advance prosecution Examiner called Attorney Simkin to request an election of species for search purposes but she did not agree to elect a single species. She requested to send another restriction for election of species. A corticosteroid, beclomethazone dipropionate was searched, the rejection is as follows.

Information Disclosure Statement

US Patent 5,300,739 is drawn to "elevator cars" and does not seem to be related to the instant formulation. Applicant is requested to send a copy of IDS filed in paper no. 2, dated 8/31/00 and references A4 and A6.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 28-45 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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It is unclear what is intended by "liquid droplets" in claim 28 (b), is this different from the droplet in (a)? (a) can have particle size less than about 50 microns in diameter, In (b) it can have less than 1000 nm, this is confusing. A clarification is required.

What is the "crystalline agent" in claim 28, part (iii)?

The term "comprising" and "comprises" cited in claim 28 is inclusive and fails to exclude unrecited steps. The use of the term comprising to introduce claimed structure means that the ingredients covered by these claims may involve more elements than those positively recited. *Ex parte Gottzein et al.*, 168 USPQ 176 (PTO Bd. App. 1969). Comprising leaves the claim open for inclusion of unspecified ingredients even in major amounts. *Ex parte Davis et al.*, 80 USPQ 448 (PTO Bd. App. 1948).

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-45 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Following reasons apply.

1. There is no support for "liquid droplet" in specification.
2. The steps of the method as claimed in claim 28 are not disclosed.

Applicant is requested to identify specific lines and page no. for the support of above cited terms.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-45 rejected under the judicially created doctrine of double patenting over claims 24-30 of U. S. Patent No. 6,264,922 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Claims 24-30 of US '922 is drawn to a method of treating a mammal comprising delivering a composition of nanoparticles to lungs, a composition which is instantly claimed is considered obvious for delivering an aerosol containing nanoparticles.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application, which matured into a patent. See MPEP § 804.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28-45 rejected under 35 U.S.C. 103(a) as being unpatentable over and Wiedmann et al. (5,747,001). And Liversidge et al. (US 5,145,684). Both the references cited teach a composition, which embraces Applicant's claimed invention. See the

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entire documents especially lines 20-67, col. 2, in '001 where an aerosol comprising nanoparticles of beclomethazone dipropionate having surface modifier on the surface, for administering to the respiratory system is taught. See lines 5-67, col. 3 and lines 1-67 in col. 4 where surface modifiers are listed.

Weidman teach the particle size less than 400 nm, whereas instant invention claims less than 1000 nm. See Tables I-III in col. 14 and claims.

Liversidge et al. teach that commercial airjet milling techniques provide particles ranging in average particle size from as low as 1,000 to 50,000 nm (1 to 50 microns). See lines 47-50, col. 1. The reference also teaches crystalline drug particle having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective particle size of less than 400 nm.

It would have been obvious to one skilled in the art to prepare additional beneficial composition for the delivery and/or treatment of respiratory system by using the composition of the crystalline drug such as steroid containing particles of size less than 1000 nm because droplets and particles of less than 400 and 1000 nm are taught by the prior art cited above. At the time of the invention instant invention would have been obvious.

The numerical limitations of the w/w ratios recited in the instant invention in claims 34-36 do not distinguish the claims over the prior art because they would have been obvious to one skilled in the art in the absence of a showing of criticality, of unobviousness or unexpected results over the prior art. It is well known that merely selecting proportions and ranges is not patentable absent a


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showing of criticality. *In re Becket*, 33 U.S.P.Q (CCPA 1937). *In re Russell*, 439 F.2d 1228, 169 U.S.P.Q. 426 (CCPA 1971).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

July 29, 2002


SABIHA QAZI, PH.D
PRIMARY EXAMINER